31611.0031

REMARKS

Claims 1 to 13, 15 and 16 are pending.

1. Claims 1 to 8, 10 to 13 and 15 are rejected under 35 USC 103(a) as being unpatentable over DeHaan et al. (U.S. Patent No. 4,542,752) in view of Mohanty et al. (Biomol Eng. 2002 Aug; 19(2-6):125-8), Allen et al. (J Biomed Mater Res. 2001 May 1; 58(3):319-28), and Cui et al. (Surface Coatings Technol 2000; 131:481-487).

DeHaan et al. describe an implantable device comprising a carbon coating over a porous substrate. The coating is of a carbon lattice formed by plasma deposition of a hydrocarbon within an energized gaseous environment. Admittedly, DeHaan et al. do not describe the structural nature of the carbon-containing coating. For that reason, the examiner has cited Mohanty et al., Allen et al. and Ciu et al. as each describing "the biocompatibility of amorphous diamond-like carbon (DLC) coating on conductive substrates." The applicants agree with the examiner on this point. However, the applicants are of the opinion that the disclosure of a DLC coating on a conductive substrate is not a new rejection, but merely cumulative in light of the previously cited Frericks et al. (U.S. Pub. No. 2004/0127966) reference.

On page 11 of the applicants' amendment filed October 18, 2005, it was pointed out that at paragraph 0003, Frericks et al. disclose that a "diamond-like carbon can be deposited using a laser, among other things. It is furthermore disclosed that the entire electrode head may be coated with a diamond-like carbon layer and thereafter the stimulation surfaces may be freed, as desired, by photoetching." The applicants pointed out in their previous amendment that this

31611.0031

would have taught one skilled in the art "that while diamond-like carbon is 'extremely biocompatible' it does not have the requisite porosity to serve as an implantable conductive surface, as taught by Frericks et al. Instead, the stimulation surface must be 'freed' through further processing to provide a high surface area material." The examiner acquiesced to this position by removing Frericks et al. as a reference with respect to its disclosure of DLC per se as a useful carbon-containing coating for an implantable electrode. The applicants further assert that each of the secondary references suffer from the same short-coming. In fact, there is nothing in any of their disclosures that would have lead one skilled in the art to any other conclusion.

Specifically, Mohanty et al. discusses a study evaluating the tissue response of DLC coated on titanium in comparison with bare titanium when implanted in the skeletal muscle of rabbits. This was for the purpose of determining biocompatibility in the skeletal muscle, which is not contested in the present application.

Likewise, Allen et al. is directed to DLC-coated cobaltchromium cylinders to study their long-term effects as total joint replacement materials. This is very similar to the focus of Mohanty et al.

Finally, Cui et al. focused their attention on DLC coatings functioning as low-friction bearing surfaces (pg. 486) for surgical instruments, implant fittings such as infusion devices and connecting parts, and semi-permanent components such as heart valves, replacement joints and opthalmics.

In that light, the applicants' assert that in addition to their presently pending claims excluding untreated or "unfreed" DLC as a carbon-containing coating, the application and

31611.0031

use of their claimed electrode is distinct from those of the cited prior art. Instead of load-bearing surfaces, and the like, amended independent claims 1, 11 and 13 cover implantable electrodes comprising a biocompatible and electrically conductive intermediate coating supported on a substrate. The intermediate coating provides the electrode with a relatively high surface area. However, as discussed at page 2, beginning at line 6, in the case of an exemplary sputtered columnar titanium nitride coating, while this material has good conductivity and high specific surface area, it degrades the electrical properties of surrounding tissue after implantation. This is the reason the present carboncontaining coating comprising amorphous carbon having a random carbonaceous structure with no covalent bonding that conforms to the surface area of the intermediate coating is needed. As discussed at page 4, line 28 to page 5, line 3, "The present electrode exhibits relatively low polarization because of the greatly increased surface area imparted by the sputtered carbon, which mimics the physical structure of conventional sputter columnar titanium nitride." Figures 6 and 7 are graphic representations of this.

It is noted that in addition to DLC, Cui et al. also teaches that carbon nitride (CN) is useful as a biocompatible coating on implants. In contrast, pending claims 5, 12 and 15, which depend from independent claims 1, 11 and 13, respectively, are directed to the carbon-containing coating being doped with nitrogen. According to the Handbook of Ceramics, Glasses, and Diamonds, Ed. Charles A. Harper, 2001, p. 141, carbon nitride and nitrogen doped carbon are chemically distinct materials. Carbon nitride is a stoichiometrically balanced compound of carbon and nitride (C₃N₄). Nitrogen doped carbon on the other hand is carbon with

31611.0031

atoms of nitrogen residing in the interstitial sites of the carbon material, but not necessarily bonded thereto.

Therefore, these are two distinct materials, which further remove Cui et al. as an impediment to the presently pending claims.

Accordingly, it is believed that independent claims 1, 11 and 13 are patentable in view of this combination of references. Claims 2 to 8, 10, 12 and 15 are allowable as hinging from patentable base claims.

Reconsideration of this rejection is requested.

2. Claims 9 and 16 are rejected under 35 USC 103(a) as being unpatentable over DeHaan et al. in view of Mohanty et al., Allen et al. and Cui et al. as applied to claims 1 to 8, 10 to 13 and 15 above, and further in view of Frericks et al. As discussed in section 1 above, the primary and secondary references are inadequate for rendering independent claims 1 and 13 unpatentable. Since claims 9 and 16 depend from these respective independent claims, they too are patentable. The Frericks et al. reference does not change this patentable status.

Reconsideration of this rejection is requested.

31611.0031

It is believed that claims 1 to 13, 15 and 16 are now in condition for allowance. Notice of Allowance is requested.

Respectfully,

Michael F. Scalise Reg. No. 34,920

Greatbatch, Inc. 9645 Wehrle Drive Clarence, New York 14031 (716) 759-5810 January 31, 2006